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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,877	09/16/2003	Richard J. Whitbourne	32286-191984	1150

26694 7590 10/23/2009

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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
10/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,877	WHITBOURNE ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47 and 49-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *58* is/are allowed.

6)☒ Claim(s) *1,3,4,8,10,11,15-22,24-27,31,34-38,47,49-57 and 59-61* is/are rejected.

7)☒ Claim(s) *2,5-7,9,12-14,23,28-30,32,33 and 39-46* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/20/09,9/15/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not certain whether "the polymer composition" refers to the composition of the primer layer, the drug reservoir layer, or both.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 4, 8, 10, 11, 15-22, 24-27, 31, 34-38, 47 49-57, 59, and 60 are rejected under 35 U.S.C. 103(a) as obvious over Fan et al. (5,620,738) in view of Pacetti et al. (6,663,662), and further in view of Fearnot et al. (5,380,299). Fan et al. disclose the invention substantially as claimed. Fan et al. disclose , at least in the abstract and in col. 1, line 62 to col. 2, line 35; col. 3, line 52 to col. 4, line 25, and col. 4, line 55 to col. 5, line 30; a stent or stent body having a coating including a single outer most drug reservoir layer or means for containing and controllably releasing an agent from the stent, the reservoir layer having a hybrid polymer composition of two or more polymers (a binder polymer and a hydrophilic polymer) or a mixture; i.e., a toughening polymer (a binder polymer) or a hybrid polymer matrix, and comprising a drug stabilizing polymer (a hydrophilic polymer or an acrylic polymer or copolymer) comprising one or more active agents, where the drug reservoir layer includes a polymer selected from the group as claimed (e.g, polyurethanes or polyacrylates), where the coating remains intact upon insertion and stent expansion, where the active agent is alloyed with and deposited throughout the polymer composition and where the layer adheres to various polymeric substrates (See col. 5, lines 9-30).

However, Fan et al. do not disclose a primer layer having a polymer composition of two or more polymers, where the primer layer composition is distinct from the drug reservoir layer polymer composition, where the primer layer is a single layer, and where the primer layer comprises means for anchoring the containing means or an anchoring polymer. Pacetti et al. teach, at least in figure 2B and col. 7, line 67 to col. 8, line 44; col. 10, line 63 to col. 11, line 45; and col. 11, line 66 to col. 12, line 34; a polymeric

primer layer (32) or anchoring means distinct from a polymeric reservoir layer (34) or containing means and active agents, where the primer layer is a single layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Pacetti et al., to includes a primer layer or anchoring means with the drug reservoir layer or containing means of Fan et al. Such a stent coating would improve bonding of the drug reservoir layer or containing means to the stent or stent body.

However, Fan et al. in view of Pacetti et al. do not disclose that the primer layer comprises two or more polymers. Fearnot et al. teach, at least in col. 3, lines 40-59, a primer layer (15) having a polymer composition of two polymers (e.g. a "combination" of hydrophobic cellulose ester and cellulose nitrate), where the primer layer composition is distinct from the drug reservoir layer (14 or 13), and where the primer layer is a single layer, where the primer layer comprises an anchoring polymer (cellulose ester or cellulose nitrate). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Fearnot et al., to include a primer layer with a plurality of polymers. Such a layer would not only improve adherence of the drug reservoir layer to the stent or stent body, it would improve infusion of the active agent to a vascular region without absorption of the active agent by the primer layer.

Fan et al. also do not disclose that the stent includes one or more image enhancing materials. Pacetti et al. further teach, at least in col. 14, lines 15-23; a stent including one or more image enhancing materials (e.g., metallic particles). It would have been obvious to one having ordinary skill in the art at the time the invention was

made to include a layer with image enhancing materials in the stent of Fan et al. Such materials, such as metallic particles, would not only aid in visualization of the stent and its location within a patient's body, they would allow the controlled release of active agents into the body.

Also, with respect to claims 16, 20, 21, 22, 27, 38, and 53-56 specifically, Fan et al. in view of Pacetti et al. and Fearnot et al. disclose the invention substantially as claimed, but do not disclose that one or more polymers have the mechanical properties as claimed, the total coating or layer thickness as claimed, and the blends of active agents as claimed. Nevertheless, Pacetti et al. teach, in col. 2, lines 29-44, that the thickness of the coating as well at the types of drugs to be applied are dependent upon the "physiological mechanism targeted." Thus, it would also be a matter of obvious design choice regarding polymers having the mechanical properties as claimed and the coating or layer thicknesses as claimed. The choices would be dependent upon the desired dosage of the drug or agent and time for the release of the drug or agent to the patient's body. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply active agents, or blends thereof, since selecting known materials on the basis of their suitability of the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

5. Claims 2, 5-7, 9, 12-14, 23, 28-30, 32, 33, and 39-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a stent including, inter alia, a coating including a primer layer of a polymer composition of two or more polymers and a drug reservoir layer having a polymer composition of two or more polymers, where the stent includes an intermediate layer between the primer layer, where the anchoring polymers have functional groups as claimed, where the primer layer comprises polymers other than cellulose ester or cellulose nitrate, and where the drug reservoir layer comprises at least nitrocellulose.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

7. Claim 58 is allowed.

8. Claim 61 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a stent having a coating including, inter alia, a primer layer and a single outermost drug reservoir layer, where each of the

layers include a hybrid polymer composition of at least one hydrophobic polymer and at least one hydrophilic polymer.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Amendment

10. Applicant's arguments with respect to rejections of claims 1, 3, 4, 8, 10, 11, 15-22, 24-27, 31, 34-38, 47 49-57, 59, 60, and 61 have been considered but are moot in view of new grounds of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yang et al. (6,258,121) teach a stent with a coating including hydrophobic and hydrophilic polymers.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773